

DI-5954 (BXTR 9004.6)
PATENTREPLY UNDER 37 CFR 1.116-EXPEDITED PROCEDURE-
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AMENDMENTS TO THE CLAIMS

JUL 03 2006

1-15. (Cancelled)

16. (Currently amended) A method of parenteral administration comprising administering a stable pharmaceutical composition to a patient by parenteral injection, wherein the composition comprises ~~comprising~~ erythropoietin and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, and wherein the composition is free of serum albumin and the derivatives are acylated, fluorinated, alpha-keto or salt forms of said peptide stabilizers, or include nitro Phe or p-amino Phe in place of Phe, or cyclohexyl Ala in place of Ala.

17. (Cancelled)

18. (Withdrawn) The composition of claim 16, wherein the peptide stabilizer is a tripeptide.

19. (Cancelled)

20. (Currently amended) The method composition of claim 16, wherein the derivatives comprise salts of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, and Ala-Ala.

21. (Currently amended) The method composition of claim 16, wherein concentration of the peptide stabilizer in said composition is between about 0.01 g/L and about 10 g/L.

22. (Currently amended) The method composition of claim 21, wherein the concentration of the peptide stabilizer is between about 0.5 g/L and about 5 g/L.

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23. (Cancelled)

24. (Currently amended) The method composition of claim 16, wherein the erythropoietin is a recombinant erythropoietin.

25. (Currently amended) The method composition of claim 24, wherein the recombinant erythropoietin is produced in BHK cells.

26. (Currently amended) The method composition of claim 24, wherein the recombinant erythropoietin is produced in CHO cells.

27. (Currently amended) The method composition of claim 24, wherein the recombinant erythropoietin is erythropoietin omega.

28. (Currently amended) The method composition of claim 27, wherein concentration of erythropoietin omega in said composition is between about 500 IU/ml and about 100,000 IU/ml.

29. (Currently amended) The method composition of claim 28, wherein the concentration of erythropoietin omega is between about 2,000 IU/ml and about 20,000 IU/ml.

30. (Currently amended) The method composition of claim 16, wherein the composition further comprises a surfactant.

31. (Currently amended) The method composition of claim 30, wherein the surfactant is a nonionic surfactant, cationic surfactant, anionic surfactant, amphoteric surfactant, zwitterionic surfactant, or a mixture thereof.

32. (Cancelled).

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33. (Currently amended) The method composition of claim 30, wherein concentration of the surfactant in said composition is between about 0.0005% w/v and about 0.5% w/v.

34. (Currently amended) A method of parenteral administration comprising administering a stable pharmaceutical composition to a patient by parenteral injection, wherein the composition comprises ~~comprising~~ erythropoietin, a polyoxyalkylene sorbitan fatty acid ester, and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, and wherein the composition is free of serum albumin and the derivatives are acylated, fluorinated, alpha-keto or salt forms of said peptide stabilizers, or include nitro Phe or p-amino Phe in place of Phe, or cyclohexyl Ala in place of Ala.

35. (Currently amended) The method composition of claim 34, wherein the erythropoietin is erythropoietin omega.

36. (Cancelled)

37. (Cancelled)

38. (Withdrawn) A stable pharmaceutical composition comprising erythropoietin and a peptide stabilizer selected from the group consisting of tetrapeptides, pentapeptides, derivatives thereof and mixtures thereof, and wherein the composition is free of serum albumin.

39. (Withdrawn) The composition of claim 38 wherein the composition is for administration by parenteral injection.

40. (Withdrawn) The composition of claim 38 wherein the composition further comprises a polyoxyalkylene sorbitan fatty acid ester.